

Claims 1-64 are pending this application. Previously, a provisional election was made by Applicants to prosecute the invention of Group I, species 1a and 2d, claims 1-5, 7-9, 11, 13-26, 28, 30-38 and 40-44. Claims 6, 10, 12, 27, 29, 39 and 45-46 were withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 14, 18, 31, 33 and 41. The amendment to these claims have been made to correct the informalities appearing in the claims and to respond to the rejections under 35 U.S.C. § 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. These amendments were not made to distinguish the invention over the cited prior art.

Applicants note that the Examiner has objected to the drawings under 37 C.F.R. § 1.83(a). In this regard, the Examiner has indicated that the Applicants should correct the drawings to show that the sheath is secured to the distal end of the catheter tube, as is required by claim 35. However, Applicants believe that such a structure is shown in FIGS. 1-6. Specific reference is made to the specification, namely page 13, lines 19-26, which states that the detachable sheath has a distal end that may be glued, bonded, heat shrunk or otherwise secured to the distal end of the catheter tube and/or the distal end of the elongated tubular member 22. The drawings show the sheath secured to

the catheter tube. Accordingly, Applicants have not submitted proposed drawing corrections with this reply but would be willing to further discuss the matter with the Examiner if requested.

Claims 1-5, 7-9, 11, 13, 16-31, 33-41, 43 and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,749,852 to Schwab, et al. (the "Schwab patent") in view of U.S. Patent No. 5,843,027 to Stone et al. (the "Stone patent"). Applicants strongly disagree with the Examiner's interpretation of the catheter assembly disclosed in the Schwab patent. The Examiner has relied on the embodiment of FIG. 12, showing perfusion openings (32) configured on a sheath, which the Examiner claims is capable of being ruptured during expansion of the expandable member. However, the Schwab patent fails to disclose or even slightly suggest that the spiral balloon (10) should be inflated or over-inflated to rupture the sheath along these openings (32). In fact, the sheath arrangement and openings (32) are not intended to rupture as such an occurrence would prevent the sheath from performing its main function. Specifically, the particular embodiment of the catheter shown and disclosed in FIG. 12 of the Schwab patent utilizes a sheath (18) with openings (32) arranged to provide a means for diverting blood flow to side vessels extending from the main vessel in which the spiral balloon (10) is positioned. This sheath (18) is provided to create

perfusion channels with the lobes of the balloon (10) to allow blood to perfuse past the expanded balloon (10). As is shown in FIG. 12, when the spiral balloon is placed in its expanded position, the sheath (18) must remain fully intact in order to provide the necessary blood flow through the openings (32) which feed the side vessels extending from the main vessel. The catheter shown in the Schwab patent must maintain the sheath (18) with openings (32) intact to adequately supply blood flow to the side vessels. The Schwab patent is completely devoid of any teaching which would suggest that the spiral balloon could be overinflated to cause the sheath to rupture since the rupturing of the sheath would destroy the blood perfusion channel and would certainly prevent the openings (32) from diverting blood flow to side branches. A rupture also could possibly cause portions of the sheath to block the channel formed between the sheath and spiral balloon. Therefore, the Schwab patent simply fails to disclose the feature of a sheath being configured to rupture during expansion of the expandable member. In fact, as expressed above, quite the opposite is taught by the Schwab patent since it would be detrimental if the sheath used in the FIG. 12 embodiment were to rupture. Accordingly, Applicants believe that the Schwab patent fails to disclose the basic concept of the present invention.

Moreover, the Stone patent fails to teach or even remotely suggest the

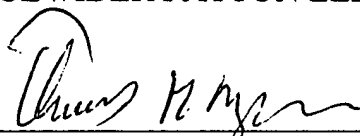
elements of the present invention. The sheath described in the Stone patent is simply used to modify the expansion characteristics of the balloon onto which a stent can be mounted. Moreover, the Stone patent fails to teach or suggest that the sheath could be ruptured or that the stent could be mounted beneath the sheath. Rather, the stent in the Stone patent is shown mounted on the outside of the sheath which is placed over the balloon to modify the expansion characteristics of the balloon. Therefore, the particular combination of the Schwab patent with the Stone patent simply fails to achieve the structure recited in the claims at issue. Applicants respectfully request the Examiner to withdraw the obviousness rejections based on these cited references.

Claims 14, 15, 32 and 42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Schwab patent in view of U.S. Patent No. 6,302,874 to Makower et al., (the "Makower patent"). As is discussed above, the Schwab patent fails to disclose the basic concept of the present invention. The Makower patent is cited for showing a catheter formed from a polyurethane. However, the Makower patent shows none of the particular combination of elements of the present invention. Therefore, the combination of the Stone patent with the Makower patent also fails to achieve the structure recited in the claims at issue. As such, Applicants respectfully request that the Examiner withdraw the obviousness rejections addressed to the present claims.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at 310-824-5555 to facilitate prosecution of this application, if necessary.

Attached hereto is a marked up version of the changes made to the specification and claims by the current Amendment. The attached page is captioned "Version With Markings To Show Changes Made."

Respectfully submitted,
FULWIDER PATTON LEE & UTECHT, LLP



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THM:mem

Enclosures:

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“VERSION WITH MARKINGS TO SHOW CHANGES MADE”

14. (Amended) The catheter assembly of claim 1, wherein:

the sheath is formed from [ESTANE] polyurethane with a shore hardness of 45D or lower.

18. (Amended) An apparatus for delivering an endoprosthesis within a body lumen, comprising:

an endoprosthesis;

means for delivering the endoprosthesis within a body lumen, the means for delivering having a proximal end portion and a distal end portion;

means for expanding the endoprosthesis, the means for expanding associated with the distal end portion of the means for delivering, wherein the endoprosthesis is disposed on the means for expanding; and

means for retaining the endoprosthesis, the means for retaining being disposed on the means for delivering and over the endoprosthesis, wherein the means for retaining is configured to [detach from the means for delivering] rupture to allow the endoprosthesis to expand into a deployed position when inflation fluid is introduced into

the means for expanding.

31. (Amended) The apparatus of claim 18, wherein:

the means for retaining is formed from [ESTANE] polyurethane.

33.(Amended) The apparatus of claim 18, wherein:

the means for retaining is formed from a material selected from the group consisting of polyurethanes, polyetheretherketone, polyether amides, [polyurethane,] copolyesters, and expandable polytetrafluoroethylene.

41. (Amended) The catheter assembly of claim 35, wherein:

the sheath is formed from [ESTANE] polyurethane.